



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-1800-N2]

Inflation Reduction Act (IRA) Revised Program Guidance

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing the availability of CMS’ revised guidance for the Medicare Part B and Part D Prescription Drug Inflation Rebate Program for the implementation of the Inflation Reduction Act. CMS will be releasing additional Inflation Reduction Act-related guidance; all can be viewed on the dedicated Inflation Reduction Act section of the CMS website.

FOR FURTHER INFORMATION CONTACT: Inquiries related to the revised guidance should be sent to IRAREbateandNegotiation@cms.hhs.gov with the relevant subject line, “Medicare Inflation Rebate Program Guidance.”

SUPPLEMENTARY INFORMATION:

The Inflation Reduction Act was signed into law on August 16, 2022. Section 11101 of the Inflation Reduction Act added a new section 1847A(i) to the Social Security Act (the Act), which establishes a requirement for manufacturers to pay Medicare Part B rebates for single source drugs and biological products with prices that increase faster than the rate of inflation for a calendar quarter to the Federal Supplementary Medical Insurance Trust Fund, and provides for lower Part B beneficiary cost sharing on these drugs and biologicals. Section 11102 of the Inflation Reduction Act added a new section 1860D-14B to the Act, which establishes a requirement for manufacturers to pay rebates to the Federal Supplementary Medical Insurance Trust Fund for certain Part D drugs when prices increase faster than the rate of inflation for each

12-month applicable period. Collectively, this program to implement these rebates is referred to as the Medicare Prescription Drug Inflation Rebate Program, or the Inflation Rebate Program.

To obtain copies of the revised guidance and the responses to comments from the initial guidance, as well as other Inflation Reduction Act-related documents, please access the CMS Inflation Reduction Act web site by copying and pasting the following web address into your web browser: <https://www.cms.gov/inflation-reduction-act-and-medicare>. If interested in receiving CMS Inflation Reduction Act updates by email, individuals may sign up for CMS Inflation Reduction Act's email updates at <https://www.cms.gov/About-CMS/Agency-Information/Aboutwebsite/EmailUpdates>.

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Vanessa Garcia, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: December 12, 2023.

Vanessa Garcia,

Federal Register Liaison,

Centers for Medicare & Medicaid Services.